IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

THE STATE OF TEXAS,
Plaintiff,

-vs-

Case No. A-12-CA-925-SS

RANBAXY PHARMACEUTICALS, INC.; RANBAXY LABORATORIES, INC.; RANBAXY USA, INC.; and RANBAXY, INC.,
Defendants.

ORDER

BE IT REMEMBERED on this day the Court reviewed the file in the above-styled cause, and specifically Plaintiff the State of Texas's Motion to Remand [#18], Defendants Ranbaxy Pharmaceuticals, Inc., Ranbaxy Laboratories, Inc., Ranbaxy USA, Inc., and Ranbaxy, Inc. (collectively Ranbaxy)'s Memorandum in Opposition [#21] thereto, Texas's Reply [#22], and Ranbaxy's Motion and Amended Motion for Leave to file Sur-Reply [##23, 24].[1] Having considered the documents, the file as a whole, and the governing law, the Court now enters the following opinion and orders, granting the motion to remand.

Background

This is an action under the Texas Medicaid Fraud Prevention Act (TMFPA), brought by the Texas Attorney General on behalf of the State of Texas, against Ranbaxy, and filed in the 345th Judicial District Court of Travis County, Texas. *See* TEX. HUM. RES. CODE § 36.052(d). Texas alleges Ranbaxy has submitted false or misleading pricing information to the Texas Health and

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[1]The original Motion for Leave is DISMISSED AS MOOT, and the Amended Motion is GRANTED.

Human Services Commission (HHSC), which in turn is asserted to have led HHSC to overestimate the prices pharmaceutical providers (such as pharmacies) are paying for the drugs, leading to excessive reimbursements to those providers by HHSC.

Ranbaxy removed the case here, asserting federal-question jurisdiction exists. Although Texas's Original Petition is not based on any federal cause of action, Ranbaxy asserts the meanings of two terms under federal law are at issue.

The two terms in question are the "Average Manufacturer's Price" (AMP) as defined by 42 U.S.C. § 1396r-8, and the "Estimated Acquisition Cost" (EAC) as defined by 42 C.F.R. §§ 447.502, .512. "Estimated acquisition cost (EAC) means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." 42 C.F.R. § 447.502. AMP is articulated by the federal statute as follows, subject to a variety of exclusions for prompt payment discounts, bona fide service fees, rebates, and other qualifying discounts:

> Subject to subparagraph (B), the term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by—
>
> (i) wholesalers for drugs distributed to retail community pharmacies; and
>
> (ii) retail community pharmacies that purchase drugs directly from the manufacturer.

42 U.S.C. § 1396r-8(k)(1)(A).

Presently, Texas has moved to remand, denying this Court possesses subject matter jurisdiction over this case.

Discussion

I. Legal Standard—Federal Question Jurisdiction

It is axiomatic that "[f]ederal courts are courts of limited jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). The courts derive the power to perform their judicial function solely from the grants of authority found in the Constitution and the various jurisdictional statutes passed by Congress. *Id.* Thus, the Court is constrained to adjudicate only those cases within the parameters of the jurisdiction vested in it by the Constitution and the Congress. The Court begins with a presumption that a suit lies outside its jurisdiction and places the burden of establishing subject matter jurisdiction on the party seeking to have the case heard in the federal forum. *Howery v. Allstate Ins. Co.*, 243 F.3d 912, 916 (5th Cir. 2001).

In general, a defendant may remove a civil action if a federal court would have had original jurisdiction over one or more of the plaintiff's claims. *See* 28 U.S.C. § 1441(a). The removing party bears the burden of establishing federal jurisdiction. *De Aguilar v. Boeing Co.*, 47 F.3d 1404, 1408 (5th Cir. 1995). District courts have "original jurisdiction of all civil actions *arising under* the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331 (emphasis added). The well-pleaded-complaint rule has long governed whether a case "arises under" federal law for purposes of § 1331. *Holmes Group, Inc. v. Vornado Air Circulation Sys.*, 535 U.S. 826, 830 (2002) (citing *Phillips Petroleum Co. v. Texaco Inc.*, 415 U.S. 125, 127–28 (1974) (per curiam)). Under this rule, federal question jurisdiction exists only where federal law is "'an element, and an essential one, of the plaintiff's cause of action.'" *Phillips*, 415 U.S. at 127 (quoting *Gully v. First Nat'l Bank*, 299 U.S. 109, 112 (1936)). The federal question "'must be disclosed upon the face of the complaint, unaided by the answer.'" *Id.* at 127–28 (quoting *Gully*, 299 U.S. at 113). Moreover, "'the complaint itself will not avail as a basis of jurisdiction in so far as it goes beyond a statement of the plaintiff's cause of action and anticipates or replies to a probable defense.'" *Id.* (quoting *Gully*, 299 U.S. at

113). The corollary is that a federal defense alone is not a basis for federal jurisdiction. *Rivet v. Regions Bank of La.*, 522 U.S. 470, 475 (1998).

Federal question jurisdiction is in turn subdivided into (1) cases in which federal law provides a cause of action, and (2) state-law claims that implicate a federal issue, also referred to as embedded federal questions. *See Grable & Sons Metal Prods. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005). *Grable* is the "touchstone" case regarding embedded-federal-issue jurisdiction. *Minton v. Gunn*, 355 S.W.3d 634, 649 (Tex. 2011) (Guzman, J., dissenting) (citing CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE AND PROCEDURE § 3562 at 187 (3d ed. 2008)), *cert. granted*, 80 U.S.L.W. 3547 (U.S. Oct. 5, 2012) (No. 11-1118).

In *Grable*, the Supreme Court has explained, "the question is, does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Id.* at 314. Broken down into elements, embedded-federal-question jurisdiction exists if: "(1) resolving a federal issue is necessary to resolution of the state-law claim; (2) the federal issue is actually disputed; (3) the federal issue is substantial; and (4) federal jurisdiction will not disturb the balance of federal and state judicial responsibilities." *Singh v. Duane Morris LLP*, 538 F.3d 334, 338 (5th Cir. 2008).

II. Application

Here, the Original Petition discloses no federal cause of action; rather, Texas is seeking to recover under state law, specifically the civil remedies and injunctive relief authorized by Texas Human Resources Code §§ 36.051, .052, which in turn punish "unlawful acts" as defined in

§ 36.002. As such, if there is a federal issue, it is embedded in the state-law claim, and therefore the Court is guided by the Supreme Court's *Grable* analysis.

Texas alleges Ranbaxy violated § 36.002 by reporting false or misleading drug prices to Texas Medicaid, or by "conceal[ing] from, or fail[ing] to disclose to Texas Medicaid the prices generally and currently paid in the marketplace for those drugs." Pl.'s Orig. Pet. [#22-2], ¶ 4.4. Specifically, Ranbaxy is alleged to have knowingly or intentionally: (1) "made a false statement or misrepresentation of material fact on an application for a contract, benefit, or payment under the Medicaid Program; or that is intended to be used to determine a person's eligibility for a benefit or payment under the Medicaid program," (2) "conceal[ed] or fail[ed] to disclose an event that permits a person to receive a benefit or payment that is not authorized, or that is greater than the benefit or payment that is authorized," and (3) "ma[de] or caus[ed] to be made, induc[ed], or [sought] to induce the making of a false statement or misrepresentation of a material fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid Program." *Id.*, ¶¶ 6.4.–.5 (citing TEX. HUM. RES. CODE § 36.002(1)(A), (B), .002(2), .002(4)).

In applying to have its drugs included in the Texas Medicaid program, Ranbaxy was required by Texas regulations to submit questionnaires for each drug, including: "the following prices for each drug they seek to have included on the TDCI: (1) the suggested average wholesale price to pharmacies; (2) *Average Manufacturer Price*; (3) price to wholesalers and/or distributors; (4) the direct price to pharmacies; (5) central purchase price to chain (such as warehouse price); (6) institutional or other contract price (Nursing Home, Home Health Care); and (7) other price." *Id.* ¶ 5.4 (emphasis added) (citing 1 TEX. ADMIN. CODE § 355.8541(2)(D)(v)). In turn, the Texas Health

and Human Services Commission, which is charged with administering Medicaid in Texas, uses the pricing information submitted in the questionnaires to establish the Estimated Acquisition Cost (EAC) of the drug in question. EAC is generally defined under federal regulations as "the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." 42 C.F.R. § 447.502. However, Texas regulations provide a definition which is both more detailed, and broader: "[EAC is]: (i) wholesale estimated acquisition cost ('WEAC'); (ii) direct estimated acquisition cost ('DEAC'), according to the pharmacist's usual purchasing source and the pharmacist's usual purchasing quantity; or (iii) maximum allowable cost ('MAC') for multi-source drugs." 1 TEX. ADMIN. CODE § 355.8541(2)(A).

Ranbaxy argues there are two embedded federal questions in Texas's Petition, asserting the meaning and construction of (1) EAC, and (2) AMB, are federal questions, sufficient to create federal jurisdiction over this case. The Court will address each in turn, beginning with EAC.

A. Estimated Acquisition Cost

Comparing the federal and Texas definition of EAC, it is readily apparent that the substance of EAC for purposes of determining whether an "unlawful act" under the TMFPA has been perpetrated is found in the Texas regulation, not the federal rule. The federal rule simply directs state agencies to generate a "best estimate," whereas the Texas regulation provides more specific guidance. As such, the Court finds EAC is not a substantial issue. Nor has Ranbaxy established there is any actual dispute as to the meaning or construction of EAC, or that resolution of any such dispute is necessary to Texas's Petition: the Court has reviewed Ranbaxy's pleadings in vain for any attempt at distinguishing how Ranbaxy and Texas would interpret 42 C.F.R. § 447.502 differently.

Finally, EAC is a value created by state agencies such as HHSC, and its precise meaning is thus irrelevant to whether Ranbaxy knowingly or intentionally submitted false or misleading pricing information to HHSC. Accordingly, Ranbaxy has failed to show any of the first three *Grable* factors are satisfied by pointing to EAC.

B. Average Manufacturer Price

This is a closer question, because AMP is a type or pricing figure drug manufacturers are required by Texas regulation to submit to HHSC in the drug questionnaires. However, it is only one price required to be submitted, among a total of seven. *See* 1 TEX. ADMIN. CODE § 355.8541(2)(D)(v). The Court cannot determine from the Original Petition, or the various pleadings, that AMP is the specific pricing figure about which Ranbaxy is alleged to have submitted false or misleading information. As such, the Court finds Ranbaxy has failed to demonstrate the meaning of AMP is actually at issue, or is a substantial issue. And Ranbaxy again fails to articulate what is disputed. Belatedly, Ranbaxy offers the following explanation, in its Sur-Reply: "The interpretation of a federal term AMP is actually disputed because, in order to prevail, Texas must establish that AMP means something other than the net prices to wholesalers or chain warehouses, whereas Ranbaxy must and will establish that AMP is the net price to wholesalers or chain warehouses." Def.'s Sur-Reply [#24-1] at 2. The Court disagrees. As alleged in the Original Petition, Texas could prevail by proving Ranbaxy submitted false information under any of the six other types of pricing information required by Texas regulations. Nor does any part of the Original Petition specifically point to AMP as the basis for Texas's cause of action. More importantly, the foregoing explanation by Ranbaxy amounts to no more than a federal defense: Ranbaxy is arguing it will prevail by proving it submitted AMP figures in compliance with the federal standard. Because

federal jurisdiction cannot rest on a defense, a remand is required. *See Rivet*, 522 U.S. at 475. Alternatively, the parties are simply arguing about whether the Texas regulation incorporated the federal definition of AMP without any additional modifications or additions, but that is a question of state law, to be determined through careful construction of the Texas regulations.

C. The Fourth *Grable* Factor

Finally, as to both EAC and AMP, the Court finds asserting federal jurisdiction would upset the balance between state and federal courts. Both EAC and AMP under federal law are broad, general terms. They set general guidelines for state Medicaid schemes, schemes which are given more specific substance by state rules, as described above. To hold that simply incorporating them by reference into the far more specific rules and standards Texas has adopted would sweep large numbers of state causes of action into federal courts, and would deprive state courts of their proper role in enforcing state Medicaid programs, frustrating the balance Congress intended.

Conclusion

Accordingly,

IT IS ORDERED that Defendants Ranbaxy Pharmaceuticals, Inc., et al.'s Motion for Leave to File Sur-Reply is DISMISSED AS MOOT;

IT IS FURTHER ORDERED that Defendants Ranbaxy Pharmaceuticals, Inc., et al.'s Amended Motion for Leave to File Sur-Reply is GRANTED;

IT IS FURTHER ORDERED that Plaintiff the State of Texas's Motion to Remand [#18] is GRANTED;

IT IS FURTHER ORDERED that this case is REMANDED to the 345th Judicial District Court of Travis County, Texas;

IT IS FINALLY ORDERED that the Clerk's office shall mail a certified copy of this Order to the Clerk of the 345th Judicial District Court of Travis County, Texas.

SIGNED this the 8th day of November 2012.

SAM SPARKS
UNITED STATES DISTRICT JUDGE